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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/696,194	10/26/2000	Derek O'Hagan	1629.002	4102

27476 7590 07/01/2003

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Intellectual Property - R440
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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/696,194

Applicant(s)

O'HAGAN ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 October 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☒ Claim(s) 18,19 and 24 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

1. Claims 1-31 are currently under examination.

Information Disclosure Statement

2. The information disclosure statements filed 23 February, and 07
5 May, 2001, have been placed in the application file and the
information referred to therein has been considered.

3. Applicants are reminded that the listing of references in the
specification (e.g., see pp. 38-41) is not a proper information
10 disclosure statement. 37 C.F.R. § 1.98(b) requires a list of all
patents, publications, or other information submitted for
consideration by the Office, and M.P.E.P. § 609 ¶ A(1) states, "the
list may not be incorporated into the specification but must be
submitted in a separate paper." Therefore, unless the references
15 have been cited or considered by the examiner on a form PTO-892 or
PTO-1449, they have not been considered.

37 C.F.R. § 1.75(c)

4. Claims 18, 19, and 24 are objected to under 37 C.F.R. § 1.75(c),
20 as being of improper dependent form for failing to further limit
the subject matter of a previous claim. Applicant is required to
cancel the claim(s), or amend the claim(s) to place the claims in
proper dependent form, or rewrite the claim(s) in independent form.
Claims 18, 19, and 24 depend from claims 20, 21, and 26,
25 respectively, and do not refer to a preceding claim. Refer to
M.P.E.P. § 608.01(n).

35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35

U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 5-12, 16, 21, 22, 24, 26-28 are rejected under 35 U.S.C. § 102(b) as being clearly anticipated by Shionoya et al. (1983). Shionoya et al. (1983) provide a method for the production of immune responses in a mammal comprising the administration of an admixture comprising an immunogen (e.g., BSA (Examples 1-4), inactivated Meth-A tumor cells (Example 5)) and a plant lectin (e.g., abrin), wherein said administration results in an immune response that is greater as compared to the immune response in the absence of the adjuvant (e.g., see Tables 2-5 and Examples 1-5). The method discloses the generation of both humoral (e.g., see Examples 1, 2, and 4) and cellular (e.g., see Examples 3 and 5) immune responses. The humoral responses included both IgG and IgM antibody production (e.g., see Example 4). Various formulations, routes of administrations, and ratios of immunogen/adjuvant were also described.

35 U.S.C. § 103(a)

7. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5 Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10 8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the
15 time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

20 9. The factual inquiries set forth in *Graham et al. v. John Deere Company of Kansas City et al.*; *Calmar, Inc. v. Cook Chemical Company*; *Colgate-Palmolive Company v. Same*, 148 U.S.P.Q. 459 (U.S. Sup. Ct. 1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are summarized as follows: 1) Determining the scope and contents of the prior art. 2) Ascertaining
25 the differences between the prior art and the claims at issue. 3) Resolving the level of ordinary skill in the pertinent art. 4) Considering objective evidence present in the application indicating obviousness or unobviousness.

30 10. Claims 2, 3, 13, 14, 17-19, 23, and 25 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shionoya et al. (1983) in view of O'Hagan et al. (1999). The teachings of Shionoya et al. (1983) have been set forth *supra* in paragraph 6. This teaching does not disclose intranasal administrations, the detection of
35 antibodies in mucosal secretions, a viral immunogen, or the

5 detection of antibody reactivity by ELISA. However, O'Hagan et al. (1999) disclose intranasal immunization protocols employing a viral immunogen (e.g., herpes simplex virus type 2 (HSV-2) glycoprotein D2) and known adjuvant (see Results, pp. 2231-2234, Figures 1 and 2, and Table 1). Antibody titers in various samples (e.g., mucosal secretions) were determined by ELISA. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute the MF59 adjuvant in the immunization protocol provided by O'Hagan and colleagues with the abrin adjuvant provided by Shionoya and associates, since the latter adjuvant induces strong humoral and cellular immune responses to various immunogens. Thus, the skilled artisan would reasonably expect the administration of a composition comprising abrin and the HSV-2 gD to induce strong humoral and cell-mediated immune responses against the viral envelope glycoprotein.

11. Claim 4 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Shionoya et al. (1983) in view of Carrano et al. (1999). The teachings of Shionoya et al. (1983) have been set forth *supra* in paragraph 6. This teaching does not disclose an immunogenic compositions comprising a lectin selected from the group consisting of ML-I, ML-II, ML-III, WGA, or UEA-1. Carrano et al. (1999) provide immunogenic compositions comprising a lectin (e.g., wheat germ agglutinin, abrin) (see claims). The inventors state that said lectins are useful for stimulating T and B cell responses. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an immunogenic composition comprising the immunogen of Shionoya et al. (1983) and one of the adjuvants provided by Carrano et al. (1999), since this would facilitate the generation of strong immune responses against the immunogen of interest.

12. Claim 15 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Shionoya et al. (1983) in view of Gough and Platt (1984). The teachings of Shionoya et al. (1983) have been set forth *supra* in paragraph 6. This teaching does not disclose an immunogenic compositions comprising two or more lectins. Gough and Platt (1984) provide immunogenic compositions comprising a lectin (e.g., lentil bean lectin, jack bean lectin (con A) (see col. 3, second paragraph). The inventors state that said lectins are useful for stimulating T and B cell mitogenesis. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an immunogenic composition comprising the immunogen of Shionoya et al. (1983) and two or more adjuvants as provided by Shionoya et al. (1983) and Gough and Platt (1984), since the presence of multiple lectins would reasonably be expected to increase the adjuvanticity of the formulation and lead to a stronger immune response against the immunogen of interest.

13. Claim 29 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Shionoya et al. (1983) in view of O'Hagan et al. (1997). The teachings of Shionoya et al. (1983) have been set forth *supra* in paragraph 6. This teaching does not disclose an immunogenic formulation comprising a microparticle carrier. However, O'Hagan et al. (1997) provides an efficient means for delivering an antigen to the target tissue of interest employing a microparticle (e.g., see columns 4-8). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an immunogenic formulation comprising the immunogen and adjuvant of Shionoya et al. (1983) with the microparticle carrier of O'Hagan et al. (1997) since this would facilitate the long-term delivery of immunogen to the site of interest.

14. Claims 20 and 31 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Shionoya et al. (1983) in view of Hodges et al. (1995). The teachings of Shionoya et al. (1983) have been set forth *supra* in paragraph 6. This teaching does not disclose an immunogenic compositions formulated as a nasal spray or for enteric delivery. However, Hodges et al. (1995) provide immunogenic compositions that can be formulated for enteric delivery or nasal delivery (see col. 13, second paragraph). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an immunogenic composition comprising the immunogen and adjuvant of Shionoya et al. (1983) in a formulation suitable for enteric or nasal administration as taught by Hodges et al. (1995) since this would facilitate the delivery of immunogen to other immunologically active sites.

15. Claim 30 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Shionoya et al. (1983) in view of Friedman et al. (1998). The teachings of Shionoya et al. (1983) have been set forth *supra* in paragraph 6. This teaching does not disclose an immunogenic formulation comprising a bioadhesive polymer. However, Friedman et al. (1998) provides an efficient means for delivering an antigen to the target tissue of interest employing a bioadhesive polymer (e.g., see columns 3-10). Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare an immunogenic formulation comprising the immunogen and adjuvant of Shionoya et al. (1983) with the bioadhesive polymer of Friedman et al. (1998) since this would facilitate the long-term delivery of immunogen to the site of interest.

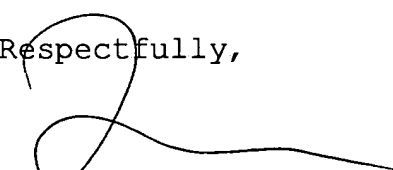
Correspondence

16. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.

17. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

18. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (703) 308-1122 or (703) 308-4027, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,


Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

13 June, 2003